Dockets Management Branch
HFA-305
Docket 2004N-0133
c/o FDA
5630 Fischers Lane
Room 1061
Rockville, MD 20852

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Comments to Docket No. 2004N-0133 - Part 11 Public Meeting; June 11, 2004

Dear Sir/Madam

Rockwell Automation is engaged in developing compliant computerized solutions and services for the lifescience industry.
We welcome the opportunity to submit comments on aspects of Part 11.

General comments:

1) The level of detail of the requirements in Part 11 are significantly different (from very high level, eg. related to validation, to very detailed, e.g. on audit trail, password aging). This limits the implementation of requirements to only a few options.

   Recommendation:
   Part 11 should be formulated in a level of detail likewith clear general requirements of 'what' should be achieved, instead of 'how'. This would support users and suppliers in finding innovative and appropriate solutions for computerized systems.

2) Risk based approach: The 'Guidance for Industry Part 11, Electronic Records; Electronic Signatures Scope and Application' focuses the application of a risk-based approach to certain controls of Part 11.

   Recommendation:
   A risk-based approach in establishing compliant solutions should be acceptable for all Part 11 requirements, not only to validation, audit trail, or archiving.
   E.g. managing system access using group accounts (logins) might be acceptable for systems that are less critical, or where procedural means (e.g. training, reverse analysis based on audit trails) can be established.

Specific Comments:

1) Administrator notification in case of security issues (§11.300(d)):
   The given criteria as to when explicit notification should be triggered seem to overlap with features like the locking of accounts and reviewing of access logs. E.g. if an email is sent after each invalid logon attempt, mailboxes will overflow. This poses high performance requirements on email servers.

   Recommendation:
   The requirements in Part 11 should be described in a more general way, in order to manage that issue uniformly within an organisation.

2) The definition of legacy systems appears too vague while applying it to the variety of systems on a typical pharmaceutical plant.

   Recommendation:
   We request additional clarification for identifying actual legacy systems. What are criteria of assessing (acceptable) changes of legacy systems, what are the expectations with resp. to technical corrective actions? (How long, i.e. after which/how many changes is a legacy system still a legacy system?)

3) Signature - record linking: Part 11 requires that a system should be capable of identifying changed or altered records, e.g. to verify the validity of a signature with respect to a given version of the record. A safe way to implement this (with significant effort) is to use digital signature mechanisms.

   Recommendation:
   We request additional clarification about acceptable less stringent solutions than digital signature mechanisms (as they are used today).

Thank you for your consideration.

With best regards

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